



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1170]

Draft Guidance for Industry on Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.” The purpose of this guidance is to assist sponsors in all phases of development of direct-acting antiviral (DAA) drugs for the treatment of chronic hepatitis C. This guidance revises and replaces a previous draft guidance for industry entitled “Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment” issued on September 14, 2010.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6360, Silver Spring, MD 20993-0002, 301-796-1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.” The purpose of this guidance is to assist sponsors in all phases of development of DAA drugs for the treatment of chronic hepatitis C. This guidance revises the draft guidance for industry entitled “Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment” issued in September 2010. Significant changes in this revision include:

- Details on phase 2 and phase 3 trial design options for the evaluation of interferon (IFN)-free and IFN-containing regimens in treatment-naïve and treatment-experienced populations, including DAA-experienced populations.

- Revised primary endpoint to sustained virologic response at 12 weeks post-treatment cessation.
- Greater emphasis on DAA drug development in special populations including trial design options for human immunodeficiency virus/hepatitis C virus co-infected patients, patients with decompensated cirrhosis, and patients pre- or post-liver transplant.
- More details on clinical virology considerations for DAA drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing DAA drugs for the treatment of chronic hepatitis C virus infection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014, the collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001, and the collections of information referred to in the guidance for industry "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under OMB control number 0910-0581.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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